

PATENT
Docket No.: HMR2041 US NPI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Application of
Kurt M. Kesseler**

Serial No.: 09/760,590

Filed: January 16, 2001

Title: Ethanol Solvate of (-)-cis-2-(2-chlorophenyl)-5,7-dihydroxy-8[4R-3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one

Examiner: Chang, C.

Art Unit: 1625

I hereby certify that this correspondence is being transmitted via facsimile to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, at (703) 872-9306, on

Date of Deposit _____

Signature _____

DECLARATION UNDER RULE 132

Commissioner for Patents

Washington, D.C. 20231

Sir:

We, Gary L. Bafus, Christine M. Harrison-Bowman and Gary Lee Silvey each declare that:

1. We are joint inventors of US Patent No. 6,576,647 that was granted from US patent application number 09/760,589, filed on January 16, 2001.

2. We employed the procedure of Kurt M. Kesseler, disclosed as Example 4 of US Patent No. 6,576,647, to prepare Form II of (-)-cis-2-(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride ethanol solvate, that is a crystalline anhydrous form of (-)-cis-2-(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride ethanol solvate characterized by X-ray diffraction pattern data presented in Table 2 of the aforesaid patent.

3. Said anhydrous Form II material is hygroscopic and absorbs moisture as is described by the relative humidity studies presented in the specification of US Patent No. 6,576,647. Said anhydrous Form II of (-)-cis-2-(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride ethanol solvate was employed as the starting material in US Patent No. 6,576,647 for the preparation of the claimed anhydrous

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or solvate-free Form I of (-)-cis-2-(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)-piperidinyl]-4H-1-benzopyran-4-one hydrochloride. Flavopiridol is another name for (-)-cis-2-(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one that is used in the specification of US 6,576,647.

4. Form II of (-)-cis-2-(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride ethanol solvate was inadvertently described as a hydrate/solvate of water/ethanol in certain sections of the specification of US 6,576,647 as noted below, and the corrected description for each section is provided.

5. Column 1, lines 36-38, reads:

The preferred form is the Flavopiridol hydrochloride ethanol/water solvate form (hereafter "Form II").

Column 1, lines 36-38 should correctly read:

The preferred form is the Flavopiridol hydrochloride ethanol solvate form (hereafter "Form II").

6. Column 3, lines 47-51, reads:

"Form II" means the solvate/hydrate of ethanol/water of (-)cis-2-(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride as described by x-ray powder diffraction in Table 2, obtained using Cu K-alpha radiation.

Column 3, lines 47-51 should correctly read:

"Form II" means the ethanol solvate of anhydrous (-)cis-2-(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride as described by X-ray powder diffraction in Table 2, obtained using Cu K-alpha radiation.

7. Column 4, lines 64-65 reads:

Form II, as a solvate/hydrate, showed a slow but continual weight gain of about 4% through about 60% Relative Humidity.

Column 4, lines 64-65 should correctly read:

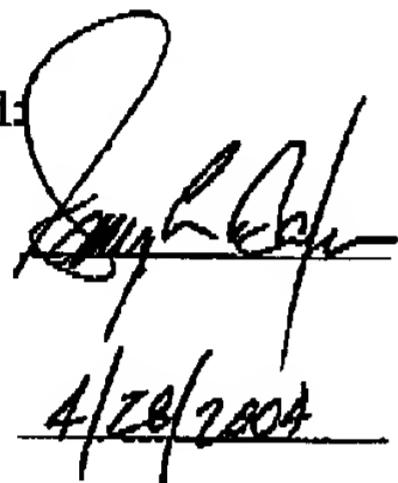
Form II showed a slow but continual weight gain of about 4% through about 60% Relative Humidity.

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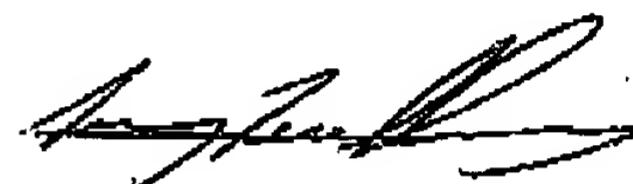
8. A request for the issuance of a certificate of correction pertaining to above paragraphs 5, 6 and 7 for U.S. Patent No. 6,576,647 has been filed with the USPTO.

9. As a person signing below, I hereby declare that all statements made herein are of my own knowledge, are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed:



Christine M. Harrison-Bowman



Date:

4/28/2004

4/28/04

4-28-04

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